REMARKS

I. Status of the Claims

Claims 53, 55 and 57 were rejected under 35 U.S.C. §103(a) over Cham et al. (Australian Patent No. 57853/80). Applicants respectfully request reconsideration of the rejection in view of the following remarks and the above amendment.

Claim 53 has been amended to expressly clarify that the composition used in the methods is "essentially free of mono- or diglycosides, free sugars and aglycones of said two glycoalkaloids and said composition has an effect that is potentiated as compared to BEC." This amendment is supported by the disclosure at page 7, lines 20-22 of the specification.

New claim 79 is presented in order to claim dependency from claim 55 which was inadvertently removed in the prior amendment.

II. The rejection under 35 U.S.C. § 103 (a) over Cham et al. should be withdrawn.

The examiner rejected claims 53, 55 and 57 under 35 U.S.C. § 103 (a) over Cham et al. (Australian Patent No. 57853/80). Applicants respectfully request reconsideration of the rejection in view of the amendments made herein and the following remarks.

Applicants previously noted that Cham et al. discloses a composition that comprises solasonine (as 33% of the composition) and solamargine (as 33% of the composition), the composition also includes a third portion which was made up of di- and mono-glycosides and free sugar (rhamnose). The composition recited in independent claim 53 does not include this third portion. Further, Applicants pointed out that the Cham et al. document provided a teaching of BEC which is a plant extract containing solarmarine, solasonine, their corresponding mono and di-glycosides, free sugars and aglucone.

In the present office action, the Examiner noted that Cham et al. at page 17 does not require the presence of di- and mono-glycosides and free sugar. Applicants

respectfully submit that the entire teaching of Cham et al. is directed to a general plant extract and not an isolated composition that contains essentially the two active ingredients being recited in the present claims. While there is a general open-ended claim at page 17 of Cham et al. the entire enablement in that specification is directed to use of just the plant extract. Moreover, the statement at page 17 of the Cham et al requires only one active component, without making any reference to the potency of such an active compound. The entire Cham et al. document provides no indication whatsoever that the presence of two glycoalkaloids together, without the presence of free sugars and aglycones has a potentiated effect as compared to the plant extract. Applicants have amended claim 53 to clarify that the claimed composition ***requires only the two glycoalkaloids*** as active ingredients and further that the composition is more effective as compared to a composition that contains the plant extract BEC.

As further evidence that the compositions used in the currently claimed methods, attached herewith a declaration from Dr. Elizabeth Williams (***originally filed in related application U.S. Serial No. 11/143,043, which is a related case***) which provides objective evidence of the efficacy and effectiveness of the presently claimed 2-glycoside component compositions as compared to BEC, the composition that is described in the Cham document. The declaration of Dr. Williams is based on data that she generated in experiments performed *circa* November 2001 and February 2002.

As noted by Dr. Williams, the BEC composition that she used was supplied by Dr. Cham (Williams Declaration ¶5). Dr. Williams performed cytotoxicity studies using BEC, solamargine and solasonine and obtained data that establishes that solamargine is considerably more potent than solasonine at killing cells (Williams Declaration ¶6). Moreover Dr. Williams shows that there is "a synergistic effect between solamargine and solasonine at the level of intracellular effect, and that BEC is not as effective as a 1:1 mixture of solasonine and solamargine alone." (Williams Declaration ¶6).

In the data shown and discussed in Williams Declaration ¶10, a BEC preparation was compared with a 1:1 mixture of purified solamargine and solasonine, and also compared to purified preparations of each of solamargine and solasonine under conditions in which receptor affinity is the predominant determinant of LD_{50}. From these

data, Dr. Williams concluded that solamargine has a higher affinity than solasonine for the cell surface receptor that mediates uptake by cells (Williams Declaration ¶11a). Further, the data support the finding of the synergistic properties of solasonine and solamargine at the point of uptake into the cell (Williams Declaration ¶11b). Importantly, these data also lead to the conclusion that the BEC composition (i.e., the composition described in Cham) is not as effective as the isolated 1:1 solamargine:solasonine mixture (Williams Declaration ¶11b).

In another set of experiments, Dr. Williams compared the effects of a BEC preparation with the effects of a 1:1 mixture of purified solamargine and solasonine or purified preparations of each of solamargine and solasonine under conditions in which the dose per cell was limiting for cytotoxic effect (Williams Declaration ¶12). These studies showed that solamargine is considerably more potent than solasonine at killing cells (Williams Declaration ¶13a) and that solamargine and solasonine have a synergistic effect at the intracellular level. Again, BEC was found to be not as effective as the isolated 1:1 solamargine:solasonine mixture (Williams Declaration ¶13b). Dr. Williams concludes that "the BEC composition is not as effective at cell killing or being taken up by the cells as a composition that consists of a 1:1 ratio of solamargine:solasonine." (Williams Declaration ¶14).

In view of the above amendments and remarks, applicants submit that the claims as presented above are non-obvious. Accordingly, the rejections should be withdrawn.

III. Conclusion

For the foregoing reasons, applicants request withdrawal of all outstanding rejections and allowance of the pending claims. No other fees are believed to be due with the filing of this paper. However, the Director is authorized to charge any additional fees deemed necessary to Deposit Account No. 13-2855, under order number 28594/41530.

If the examiner believes that a telephone conversation would expedite allowance of the claims, she is invited to contact the undersigned at the number below.

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Respectfully submitted,

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